HIV Incidence Surveillance Utilizing Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS)

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HIV Incidence

In 2003, the State of Indiana received federal funding from the Centers for Disease Control and Prevention (CDC) to incorporate HIV Incidence Surveillance into Core HIV/AIDS Surveillance activities. Indiana was one of twenty-four (24) surveillance areas to be funded. The office of Clinical Data and Research (CDR) within the Division of HIV/STD of the Indiana State Department of Health (ISDH) is responsible for this task.

The CDC developed the Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS) strategy to look at HIV infection in groups of people. STARHS evolved from a need to determine national HIV incidence rates and provide data that will accurately characterize current HIV transmission in the United States. STARHS was also developed to more effectively target HIV prevention efforts. More specifically, STARHS allows for the determination of whether people with newly reported cases of HIV were infected within the past year. STARHS includes an additional test performed on the original diagnostic serum specimens from people with newly reported HIV infections, and does not require an additional blood specimen. Informed consent is required for STARHS. A short questionnaire will also be used to obtain information about testing history patterns of each individual, in order to calculate a statistical weight for the HIV incidence estimation.

Individual eligibility requirements for STARHS include the following[1]:

- ≥ 18 years of age
- Residing in Indiana
- Able to provide informed consent
- Have a newly documented confirmatory laboratory diagnosis of HIV infection, tested confidentially, not previously reported to HIV/AIDS Reporting System (HARS)

Individuals are ineligible for STARHS if they have a diagnosis of AIDS (persons with AIDS may have low antibody levels that look like new seroconversion), or if the individual is taking antiretroviral HIV medicine (persons on Highly Active Antiretroviral Treatment may have low antibody levels that look like new seroconversion).

Specimens that are identified for STARHS will be prepared and shipped by the Indiana State Public Health Laboratory to a CDC Regional STARHS Laboratory. Testing results will be returned to ISDH and entered in the HIV incidence database for review and analysis by the CDC.

The STARHS test itself uses a dual-test strategy for detecting persons with recent HIV infection. Serum specimens that are reactive on the standard sensitive enzyme-linked immunosorbent assays (EIA) and confirmed HIV positive by Western blot (a.k.a. routine diagnostic HIV test) are retested using a modified, less sensitive EIA. Specimens reactive on the sensitive EIA but non-reactive on the less sensitive EIA are considered to represent likely recent HIV infections[2]. This test allows for the estimation of HIV incidence in the Indiana. Previous testing and reporting has only allowed the ISDH to track prevalence. By utilizing the STARHS method, ISDH has the ability to track HIV incidence rates more accurately.

Some of the potential uses of this information are[1]:

- to differentiate between recent and long-term HIV infections
- to estimate HIV incidence by identifying persons with seroconversion in previous year
- to assist prevention programs in developing prevention strategies to target at-risk individuals
- to monitor and control the spread of HIV.

The STARHS test for HIV incidence is not accurate enough to provide individual results to participants at this time. Scientific data regarding the sensitivity and specificity of STARHS are still limited, and future tests developed for incidence may or may not allow for individual results. All information gathered from this project will allow for population-based estimates of HIV incidence in Indiana, rather than individual estimates.

The ISDH plans to implement STARHS testing among Counseling, Testing and Referral (CTR) sites beginning in spring/summer of 2004. Expansion of the project to private physicians is expected in 2005. Due to the experimental aspect of STARHS and subsequent Investigational New Drug designation by the Food and Drug Administration (FDA), there are specific requirements and restrictions. The use of STARHS requires ISDH to obtain Institutional Review Board approval and allow a 30-day review of Indiana's protocol by the FDA, prior to implementation in Indiana.

Overall, HIV Incidence surveillance and STARHS will improve the ability of HIV surveillance staff to monitor changes in demographics, transmission mode and geographic distribution of new cases in Indiana. Anyone who has questions concerning the HIV Incidence Surveillance study utilizing STARHS, please contact:

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References:

1 4th HIV Incidence Consultation, Strategies & Procedures for Implementation, March 25-27, 2003, Atlanta, GA.

2 Overview of CDC STARHS Research Studies and the FDA IND, 2003.